REMARKS

Claims 1-36 are pending in this application. Claims 26 and 32 have been canceled. No new matter has been added. Applicants respectfully request reconsideration of the restriction requirement in view of the following remarks.

Claims 1-36 have been subjected to a Restriction Requirement under 35 U.S.C. §121 and §372 as follows:

Group I, claims 1-26 and 36, drawn to a pharmaceutical formulation comprising flutamide; and

Group II, claims 26-35, drawn to a process for the preparation of a pharmaceutical formulation comprising flutamide.

The Examiner suggests that the inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

The Examiner acknowledges that the claims share the common technical feature flutamide; however, it is suggested that because this element is shown in the prior art, it cannot be a special technical feature under PCT Rule 13.2. It is suggested that Neri (U.S. Patent Nos. 3,995,060 and 4,474,813) respectively teach the method for the preparation of flutamide and a pharmaceutical composition in the form of a capsule, tablet, and suppository among other forms, comprising flutamide. The Examiner concludes that no special technical features exist among the different groups because the inventions in Groups I-II fail to make a contribution over the prior art.

It is further suggested that the application contains claims directed to more than one species of the generic invention which are deemed to lack unity of invention because they are not so

linked as to form a single general inventive concept under PCT Rule 13.1. The Examiner requires the election of a single species of pharmaceutical formulation to which the claims shall be restricted if no generic claim is finally held to be allowable. Claim 1-4, 16, 18-20, 25-28, 31-32 and 36 have been considered generic.

As an additional requirement, it is suggested that with the election of either of the above groups, a provisional election of species of pharmaceutical formulation is required. In order for this election to be considered fully responsive to this requirement the election must include:

a) a specific surface-active substance of claims 1-4, 16-20, 27-28 and 36, for example sodium dodecylsulphate as enumerated in claim 17;

b) a specific flow regulator of claim 2, for example magnesium stearate as listed in the last line of page 9 of the specification;

c) a specific excipient of claims 25 and 31, for example on excipient from the list on page 9 of the specification;

d) a specific further pharmaceutical active ingredient other than flutamide of claims 26 and 32;

e) the location of the species within the claims or the specification;

f) the claims that read on the elected species, including any claims subsequently added.

The Examiner has required restriction between product and process claims and acknowledges that where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that

depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. Applicants respectfully disagree and traverse this restriction requirement and election of species.

The present invention relates to a process that enables unmilled flutamide to have bioequivalence. This bioequivalence is achieved by intensively mixing the unmilled flutamide with a surface-active substance. It has been surprisingly found that solubilization of the unmilled flutamide increases with the time of mixing. When the fine surface-active substance molecules have covered the unmilled flutamide particle surface, optimum solubility is achieved. This is a totally different approach from that of the prior art which suggests that the required blood level can only be achieved by reducing particle size to increase surface, an effect achieved through milling. In this regard, the process of the present invention eliminates the need for time-consuming and costly milling of flutamide and enables the use of particles with an average diameter of 30 microns.

Therefore, the common technical feature linking Groups I and II is the combination of unmilled flutamide with a surface-active substance, not just flutamide as stated by the Examiner. Indeed, while column 15 (lines 35-37) of U.S. Patent No. 3,995,060 describes blending milled 4'-nitro-3'-trifluoromethylisobutyranilide with starch in a suitable mixing vessel, the teachings of the applied references do not appear to suggest the use of unmilled flutamide. Therefore, Groups I-II do relate to a single general inventive concept under PCT Rule 13.1 as they make a contribution over the prior art with the special technical feature of unmilled flutamide. As such, Applicants

respectfully request reconsideration of the restriction of Group I and Group II claims.

In addition, in so far as Group I and Group II claims are drawn to product and process, Applicants respectfully submit that no additional burden would be placed upon the Examiner in searching together the subject matter of Group I and Group II. In particular, it is submitted that a search of the claimed method is coextensive with the formulation produced by that method.

Moreover, Applicants respectfully traverse the required election of species in this case. Each of the surface-active substances, flow regulators, excipients, and pharmaceutically active ingredients are functioning in the same manner in the instant formulation. As such, a search of each species within the genera is co-extensive and no serious burden would be incurred by the Examiner in searching and examining the genera. In contrast, the prosecution of each of the disclosed species in each Group of inventions separately will pose a substantial economic burden on Applicants. Therefore, reconsideration of this species election is respectfully requested.

However, in an earnest effort to be completely responsive, Applicants hereby elect to prosecute Group I, claims 1-26 and 36, drawn to a pharmaceutical formulation comprising flutamide, with traverse. Applicants also make the provisional election of the following species:

a) sodium dodecylsulphate as surface-active substance (see claim 17);

b) magnesium stearate as flow regulator (see paragraph [0072]); and

c) microcrystalline cellulose as excipient (see paragraph [0061]), with traverse.

In so far as Applicants have canceled claims 26 and 32, withdrawal of the election a further pharmaceutical active ingredient is respectfully requested.

Respectfully submitted,

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